

Docket No. 20488/57

34SEY

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT:

Kühn-Wache et al.

ART UNIT: Not yet assigned

SERIAL NO.:

10/667,200

FILED:

September 18, 2003

FOR: SECONDARY BINDING SITE OF DIPEPTIDYL PEPTIDASE

IV (DP IV)

CERTIFICATE OF MAILING

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

andva Sandra J. Wittrup

INFORMATION DISCLOSURE STATEMENT SUBMITTING REFERENCES ON COMPACT DISC

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Date: November 19, 2003

Pursuant to Applicant(s) duty of disclosure, the information listed in the attached form PTO-1449 is brought to the attention of the Examiner.

The citation of the listed items is not a representation that they constitute a complete or exhaustive listing of the relevant art or that the references are prior art. The items listed are submitted in good faith, but are not intended to substitute for the Examiner's search. It is hoped, however, that in addition to apprising the Examiner of these particular items, they will assist in identifying fields of search and in making as full and complete a search as possible.

The filing of this information disclosure statement is not an admission that the information cited herein is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

Attorney's Docket: 20488/57

U.S.S.N.: 10/667,200

Page 2 of 14

In accordance with the requirement under 37 C.F.R. 1.98 (3)(i), the following are concise explanations of the relevance, as presently understood, with regard to those items submitted herewith that are not in the English language:

I. LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION

The patents, publications or other information submitted for consideration by the Office are listed on PTO-1449, attached hereto.

II. COPIES

a. 🔯 Submitted herewith on Compact Disc is a legible copy of (i) each U.S and foreign patent; (ii) each publication or that portion which caused it to be listed; and (iii) all other information or that portion which caused it to be listed.

III. CONCISE EXPLANATION OF THE RELEVANCE

(check at least one box)

- a. [] Except as may be indicated below in (b), all of the patents, publications or other information are in the English language or were cited in an English language Search Report, a copy of which is attached hereto (concise explanation not required).
- b. 🖂 A concise explanation of the relevance of all patents, publications or other information listed that is not in the English language is as follows:

FRENCH LANGUAGE FR 2 696 740 Applicants have relied on an English language abstract in determining that this patent apparently relates to Dimethylbiguanide drug derivatives and their medical applications.

FRENCH LANGUAGE FR 2 085 665 Applicants have relied on an English language abstract in determining that this patent apparently relates to biguanide substitutes possessing a hypoglycemic property.

GERMAN LANGUAGE DT 25 42 598 A1 Applicants have relied on an English language abstract in determining that this patent apparently relates to biguanide salts as well as a method for preparing such salts. In addition to this the invention apparently covers pharmaceutical compounds which contain such salts.

Attorney's Docket: 20488/57 U.S.S.N.: 10/667,200

Page 3 of 14

GERMAN LANGUAGE WO 97/40832 Applicants have relied on an English language abstract in determining that this patent apparently relates to the use of a method for reducing in the blood of a mammal by administration of effectors the enzyme activity of dipeptidyl peptidase (DP IV) or enzyme activity similar to DP IV, the endogenous (or additionally exogenously administered) insulinotropic peptide gastric inhibitory polypeptide 1-42 and glucagon-like peptide amide-1 7-36 are decomposed in a causal sequence to a reduced extent by DP IV enzymes or those similar to DP IV.

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JAPANESE PATENT JP 4-334357A2: Applicants have relied on an English language abstract in determining that this patent ACYL DERIVATIVE HAVING ENZYME-INHIBITING ACTION, apparently relates to a compound having a prolyl endopeptibase activity-inhibiting action and useful as an antidement agent, especially an anti-amnestic agent.

GERMAN LANGUAGE DE 299 09 210 U1 Applicants have relied on an English language abstract in determining that this patent apparently relates to dipeptide compounds or compounds analogous to dipeptide compounds, which are made of an amino acid and a thiazolidine or pyrrolidine group, and to their salts. The invention further relates to the use of these compounds in the treatment of impaired glucose tolerance, glucosuria, hyperlipidemia, metabolic acidosis, diabetes mellitus, diabetic neuropathy and nephropathy as well as secondary diseases of diabetes mellitus in mammals.

GERMAN LANGUAGE DE 198 26 972 A1 Applicants have relied on an English language abstract in determining that this patent apparently relates to the use of inhibitors (I) of dipeptidyl peptidase IV (DP IV) or analogous enzymes for inhibiting the activation and proliferation of keratinocytes (including malignantly transformed keratinocytes) and tumor cells derived from keratinocytes.

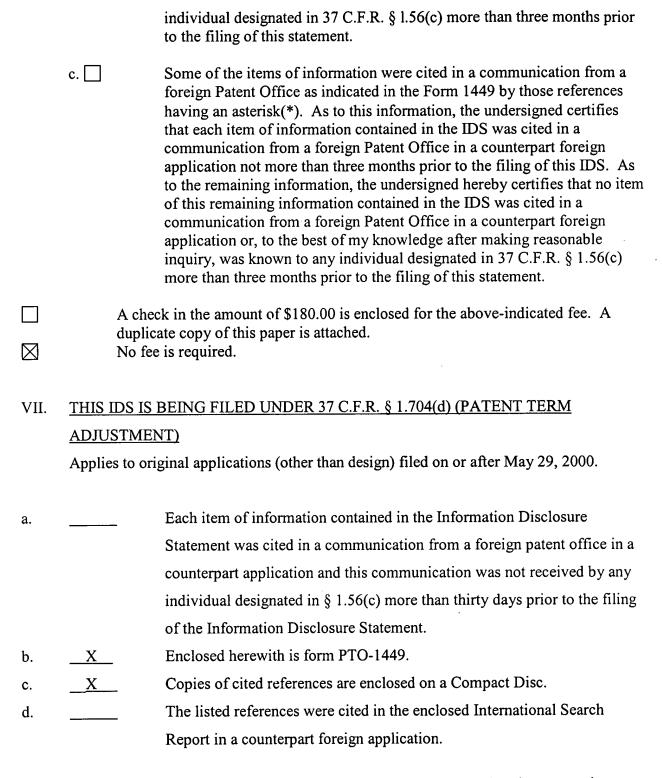
GERMAN LANGUAGE WO 99/61431 Applicants have relied on an English language abstract in determining that this patent apparently relates to dipeptide compounds or compounds analogous to dipeptide compounds, which are made of an amino acid and a thiazolidine or pyrrolidine group, and to their salts. The invention further relates to the use of these compounds in the treatment of impaired glucose tolerance, glucosuria, hyperlipidemia, metabolic acidosis, diabetes mellitus, diabetic neuropathy and nephropathy as well as secondary diseases of diabetes mellitus in mammals.

Attorney's Docket: 20488/57 U.S.S.N.: 10/667,200 Page 4 of 14

	c. 🗌	The following additional information is provided for the Examiner's consideration:
		<u>FEES</u>
ĺV.	THIS IDS IS (check one bo	BEING FILED UNDER 37 C.F.R. § 1.97(b) ox)
	a. 🔀	within three months of the filing date of a national application (37 C.F.R. § 1.97(b) (1)). No fee or certification is required.
	b. 🗌	within three months of the date of entry of the national stage as set forth in §1.491 in an international application (37 C.F.R. § 1.97(b) (2)). No fee or certification is required.
	c. 🗌	before the mailing date of a first Action on the merits (37 C.F.R. § 1.97(b) (3)). No fee or certification is required. In the event that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the certification under 37 C.F.R. § 1.97(e)below, or, if no certification has been made, charge our deposit account a fee in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p).
V.	THIS IDS IS (check one bo	BEING FILED UNDER 37 C.F.R. § 1.97(c):
	1.97(c) (1)) o	ailing date of a Final Office Action under 37 C.F.R. § 1.113 (See 37 C.F.R. § r before the mailing date of a Notice of Allowance under 37 C.F.R. § 1.311 R. § 1.97(c) (2)).
	a. No ce	rtification; therefore, a fee in the amount of \$180.00 is required by 37 C.F.R. § 1.17(p).
	b. See th	or e certification below. No fee is required.
VI.	CERTIFICAT	TION UNDER 37 C.F.R. § 1.97(e) (check only one box)
The u	ndersigned here	eby certifies that
	a. 🗌	each item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS; or
	b. 🔲	no item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application or, to the best of my knowledge after making reasonable inquiry, was known to any

Attorney's Docket: 20488/57 U.S.S.N.: 10/667,200

Page 5 of 14



If the Examiner has any questions concerning this IDS, the Examiner is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the

Attorney's Docket: 20488/57 U.S.S.N.: 10/667,200

Page 6 of 14

PTO is requested to consider this IDS under the proper rule (with a petition, if necessary) and charge any additional fees to Deposit Account No. 50-0369.

Date: November 19, 2003

Respectfully submitted,

John C. Serio, Reg. No. 39,023

BROWN RUDNICK BERLACK ISRAELS LLP

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FORM PTO-1449
INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO. **20488/57**

SERIAL NO. 10/667,200

APPLICANT(S): Kühn-Wache et al.

FILING DATE: September 18, 2003

ART UNIT:
Not Yet Assigned

UNITED STATES PATENT DOCUMENTS

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EXAM. INITIAL		DOCUMENT NUMBER	DATE	INVENTOR	CLASS	SUB CLASS	FIL. DATE IF APPR
-	AA	2,961,377	11/22/1960	Shapiro et al.	167	65	
	AB	3,174,901	03/23/1965	Sterne	167	65	
	AC	3,879,541	04/22/1975	Kabbe et al.	424	326	
	AD	3,960,949	06/01/1976	Ahrens et al.	260	564 B	
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	AF	4,935,493	06/19/1990	Bachovchin et al.	530	331	
	AG	5,433,955	07/18/1995	Bredehorst et al.	424	94.3	
	AH	5,462,928	10/31/1995	Bachovchin et al.	514	19	
	AI	5,512,549	04/30/1996	Chen et al.	514	12	
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	AW	6,124,305	09/26/2000	Villhauer	514	272	
	AX	6,172,081	01/09/2001	Damon	514	307	
Examiner:				Date:			

INFORMA'	FORM PTO-1449 FION DISCLOSURE ST	ATEMENT	ATTY. DOCKET NO. 20488/57	1	ERIAL NO. 10/667,200	
			APPLICANT(S): Kühn-Wache e	t al.		
			FILING DATE: September 18, 2003		ART UNIT: Yet Assign	ed
		UNITED STATI	ES PATENT DOCUMENTS			
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		FOREIGN P	PATENT DOCUMENTS	. -		
	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRAN Y/N
BA	WO 01/62266 A2	08/30/2001	PCT	A61K	38/00	Y
ВВ	WO 00/53171	09/14/2000	PCT	A61K	31/155	Y
BC	DT 25 42 598 A1	04/22/1976	Germany	C07C	129/16	N
BD	FR 2 696 740 A1	04/15/1994	France	C07D	207/404	N
BE	FR 2 085 665	12/31/1971	France	A61K	27/00	N
BF	WO 97/40832	11/06/1997	PCT	A61K	31/425	Abstract only
BG	WO 95/15309	06/08/1995	PCT	C07D	207/16	Y
ВН	JP 4334357	11/20/1992	Japan	C07C	233/57	Abstract only
BI	WO 93/08259	04/29/1993	PCT	C12N	<u> </u>	Y
ВЈ	WO 95/11689	05/04/1995	PCT	A61K	37/00	Y
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BM	WO 95/29691	11/09/1995	PCT	A61K	38/00	Y
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ВО	WO 00/01849	01/13/2000	PCT	C12Q	1/68	Y
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	FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT							
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		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRAN Y/N	
	вт	EP 0 995 440 A1	04/26/2000	EPO	A61K	31/425	N	
1	BU	WO 91/11457	08/08/1991	PCT	C07K	7/34	Y	
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I	3W	WO 98/19998	05/14/1998	PCT	C07D	207/00	Y	
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E	BAE	WO 00/10549	03/02/2000	PCT	A61K	31/00	Y	
F	BAF	WO 01/74299 A2	10/11/2001	PCT	A61K		Y	
E	BAG	WO 02/20825 A1	03/14/2002	PCT	C12Q	1/00	Y	
E	BAH	WO 01/89569 A1	11/29/2001	PCT	A61K	45/06	Y	
ı	BAI	WO 99/62914	12/09/1999	PCT	C07F	5/02	Y	
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Examiner:				Date:				

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ATTY. DOCKET NO. SERIAL NO. **FORM PTO-1449** INFORMATION DISCLOSURE STATEMENT 10/667,200 20488/57 APPLICANT(S): Kühn-Wache et al. ART UNIT: FILING DATE: September 18, 2003 Not Yet Assigned OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.) Campbell, I.W. New Antidiabetic Drugs, ed. C.J. Bailey & P.R. Flatt, Smith-Gordon, "Sulphonylureas and metformin: CA efficacy and inadequacy". 3:33-51 (1990). CHEMICAL ABSTRACTS, vol. 115. No. 15, 14. October 1991 (1991-10-14) Columbus, Ohio, US; abstract no. CB 149947q, SCHOEN EKKEHARD ET AL: "Dipeptidyl peptidase IV in the immune system. Effects of specific enzyme inhibitors on activity of dipeptidyl peptidase IV and proliferation of human lymphocytes" CHEMICAL ABSTRACTS, vol. 118, no. 25, 21. June 1993 (1993-06-21) Columbus, Ohio, US; abstract no. 255342k, CC Hosoda, et al, "Preparation of N-(heterocyclic Carbonyl) Amino Acids and Analogs as Prolyl Endopeptidase Inhibitors", November 1992 (1992-11-20) CHEMICAL ABSTRACTS, vol. 126, no. 2, 13. January 1997 (1997-01-13) Columbus, Ohio, US; abstract no. 16161j, CD STOECKEL A. ET AL: "Competitive inhibition of proline specific enzymes by amino acid thioxopyrrolidides and thiazolidides". Martindale The Extra Pharmacopoeia, 30th Edition, London Pharmaceutical Press, 1993, Page 1619. CE AMASHEH, S., et al., "Electrophysiological analysis of the function of the mammalian renal peptide transporter CF expressed in Xenopus Laevis oocytes". J. Physiol. 504, 169-174 (1997) Arai ET AL., "Synthesis of prolyl endopeptidase inhibitors and evaluation of their structure-activity relationships: in CG vitro inhibition of prolyl endopeptidase from Canine Brain" CHEMICAL AND PHARMACEUTICAL BULLETIN., Bd. 41, No. 9, 1993, pages. 1583-1588. DURINX, C.; et al.; "Reference Values for Plasma Dipepidyl-Pepidase IV activity and their Association with Other CH Laboratory Parameters". Clin Chem Lab Med 2001, February; 39 (2):155-9, 1 page. GOSSRAU, R.: "Cytochemistry of Membrane Proteases". Histochem J, 1985, July; 17 (7):737-71, 1 page. CI HAHN, T.; et al.; "Enzyme Histochemical Evidence for the Presence of Potential Blood Pressure Regulating Proteases in CJ Cultured Villous Explants from Human First Trimester Placentae". Acta Histochem 1993, December, 95 (2):185-92, 1 page. HEYMANN, E. et al., "Has Dipeptidyl Peptidase IV an Effect on Blood Pressure and Coagulation." Klin Wochenschr, CK 1984, January, 2;62 (1):2-10, 1 page. CL Lin, J. et al.: "Inhibition of depeptidyl peptidase IV by fluoroolefin-containing n-peptidyl-O-hydroxylamine peptidomimetics" PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES OF USA, Vol. 95, November 1998, pages 14020-14024. KOROM, S., et al "Inhibition of CD26/dipeptidyl peptidase IV activity in vivo prolongs cardiac allograft survival in rat CM recipients", Transplantation, Vol. 63, 1495 – 1500 No. 10 (1997) MAGYAR, C.E. et al., "Proximal Tubule Na Transporter Responses are the same during Acute and Chronic CN Hypertension." Am J. Physiol Renal Physiol, 2000, August; 279 (2):F358-69, 1 page. Martindale The Extra Pharmacopoeia, 30th Edition, London Pharmaceutical Press, 1993, Page 36. CO Date: Examiner:

INFORM	FORM PTO-1449 ATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 20488/57	SERIAL NO. 10/667,200		
		APPLICANT(S): Kühn-Wache et a			
		FILING DATE: September 18, 2003	ART UNIT: Not Yet Assigned		
	OTHER DOCUMENTS (INCLUDING A	AUTHOR, TITLE, DATE, PERTINEN	T PAGES, ETC.)		
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CS	TANKA, S., et al., "Suppression of arthritis 19, No. 1 Pages 15-24, (1997)	by the inhibitors of dipeptidyl peptidase	IV". <u>Int. J. Immunopharmacol</u> , Vol		
. CT	The Merck Index, 11 th Edition, An Encyclo	pedia of Chemicals, Drugs, and Biologica	als, 1989, Page 934		
CU	The Merck Index, 12 th Edition, An Encyclo	pedia of Chemicals, Drugs, and Biologica	als, 1996, Page 1014.		
CV	Deacon et al., <u>Journal of Clinical Endocrinology and Metabolism</u> , "Degradation of Glucagon-Like Peptide-1 by Huma Plasma in Vitro Yields and N-Terminally Truncated Peptide That Is a Major Endogenous Metabolite in Vivo", (1995) 80(3): 952-957.				
CW					
CX					
CY	Gutniak et al., New England Journal of Me Normal Subjects and Patients With Diabete		agon-like peptide-1 (7-36) Amide in		
CZ	H.A. Smith et al., Veterinary Pathology (for (1972), p 1018-1020.	urth edition), "Diseases and Disorders of	Metabolism: Deficiency Diseases",		
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CAB	Hoffmann et al., <u>Journal of Chromatograph</u> and non-substrate X-X-Pro- oligopeptides a				
CAC	Index Nominum, International Drug Director	ory 1992/1993, Medpharm Scientific Pub	lishers, pages 728-729.		
CAD	Mannucci et al., <u>Diabetes Care</u> , "Effect of Nondiabetic Subjects", 24(3): 489-494, Ma		GLP-1) and Leptin Levels in Obese		
CAE	Nauck et al., <u>Diabetologia</u> , "Normalization in Type 2 (non-insulin-dependent) diabetic		glucagon-like peptide 1 (7-36 amide		
CAF	Pauly et al., Regulatory Peptides, "Abstract Peptides", July 15, 1996, 64(1-3): 148 plus		nal Symposium on Regulatory		
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CAI	The Merck Index, An Encyclopedia of Chemi	icals and Drugs, 9th Edition, Merck & C	Co., Inc., 1976, page 773		
CAJ	C.B. Welch, Medical Management of Non-Instance Association, "Diagnosis and Classification" p	sulin-Dependent (Type II) Diabetes, 3 rd p. 3, 1994, Pharmacologic Intervention	edition, American Diabetes (2 pages).		
CAK	WETZEL, W., et al., "Effects of the CLIP fra Neuropeptides, 31, 41- 45 (1997)	gment ACTH 20-24 on the duration of	REM sleep episodes".		
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CAT	Hyun Sook Lee et al., "Cathepsin B Inhibitor	ry Peptides Derived from β-Casein," <u>Peptides</u> 21 (2000) 807-809.			
CAU	Nathan et al., <u>Diabetes Care</u> , "Insulinotropic Asubjects", February 1992, 15(2): 270-275.	Action of Glucagonlike Peptide-1-(7-3	7) in Diabetic and Nondiabetic		
CAV					
CAW	Pschyrembel, Kininisches Wörterbuch 257, A	Auflage, (1994), 9 pages.			
ner:		Date:			

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•				G DATE: er 18, 2003	ART UNIT: Not Yet Assigned
		OTHER DOCUMENTS (INCLUDING AU	J THOR, TITLE, I	DATE, PERTINEN	T PAGES, ETC.)
	CAX	Snow et al., Advances In Medicinal Chemistr Immunosuppressive Agents", Vol. 3, (1995),		nhibitors of Dipeptio	lyl Peptidase IV: A New Class of
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	CAZ	Vidal, (1993), 69 th Edition, p. 612-613.			
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